

Docket No.: 01-11 US**REMARKS**

Amendment to the specification has been made in order to receive the benefit of the earlier PCT filing date under 35 U.S.C. 371. In addition, claims 21 and 31 have been amended to overcome the Examiner's objections thereto.

All the claims 21-58 have been rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over WO 97/25606 to Rasmussen in view of U.S. 6,164,144 to Berg and U.S. 4,268,279 to Shindo, et al.

In this rejection, the Examiner acknowledges that neither Rasmussen or Berg teach permeability of a hollow fiber to analyte. The Examiner relies on Shindo, et al. for teaching a process comprising allowing a liquid to contact the inside of a micro-porous hollow fiber and a fluid to contact the outside when gaseous components are contained in the fluids are allowed to permeate inside and outside of the fiber.

The Applicants submit that there is no teaching whatsoever in Shindo, et al. for transport of the analyte from a sample solution through a membrane wall and into the acceptor solution. Shindo, et al., as specifically set forth in column 1, beginning at line 5, is directed to a gas transfer process. There is no teaching, suggestion or hint of transport of a dissolved analyte through a membrane wall.

The Examiner stated that it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to use a magnetic stirring bar, a hollow fiber permeable to analyte and an acidified acceptor solution as taught by Berg and Shindo, et al. with the invention of Rasmussen. The Examiner's reference to a magnetic stirring bar is inappropriate since none of this language appears in any of the claims 21-58.

As earlier pointed out by the Applicants, the apparatus and method claims of the present application define the invention as including transport of analyte through a membrane wall of a second hollow container disposed within a solution comprising a dissolved analyte. Further,

Docket No.: 01-11 US

method claims 38-51 define a process for allowing analyte equilibrium to be established between a sample solution and an acceptor solution through a membrane wall. There is no gas transfer in this arrangement.

As earlier argued by the Applicants, each of the Rasmussen and Berg references relate to structure and methods for the separation of an analyte using a surface phenomenon.

Rasmussen, for example, provides for a method for immobilization of a solvent on the surface of a carrier and contacting the surface modified carrier with a material to concentrate and fix the substance to be analyzed on the surface and thereafter desorbing the concentrated substance from the carrier surface.

Similarly, Berg utilizes a surface phenomenon. While Berg discloses a needle 24, it includes a stationary phase 32 which covers an inner surface of the needle. Absorption and desorption of materials from a stationary phase 32 is taught. Contrary to these disclosures, the present invention is directed to an apparatus and a device for carrying out liquid-liquid microextraction or liquid-liquid-liquid microextraction utilizing a membrane wall permeable to an analyte (not a gas) in which the analyte of interest passes through the membrane wall and is collected on an opposite side of the membrane wall than a side exposed to the sample solution with a dissolved analyte.

The transfer of a liquid analyte through the membrane is totally opposite to the teachings of the newly cited reference Shindo, et al. which maintains separation of fluids while passing gas from the fluids through a membrane.

In this rejection, the Examiner's is attempting to limit the focus of inquiry to structural difference from the prior art and then to show that the difference alone would have been obvious. This is not proper under the statute which requires that the invention be considered "as a whole" CrI Schenck AG v. Nortron Corporation, 218 U.S.P.Q. 698 (CAFC 1983).

Docket No.: 01-11 US

Further, the combination suggested by the Examiner is improper since references cannot be properly be combined if the effect would destroy the invention on which one of the reference patents is based. Ex parte Hartmann, 186 U.S.P.Q. 366 (PT TM Board of Appeals 1974).

Such as the case at hand, the Shindo, et al. invention is based upon the separation of two liquids and the transfer of gas from one liquid to another while maintaining separation of the two liquids. This is totally in contrast to the present invention in which the transfer of a liquid analyte through the membrane is fundamental. Transfer of analyte through membrane would not keep the two liquids of Shindo, et al. separated.

The Applicants submit that there must be some logical reason apparent from positive, concrete evidence of record that justifies the combination of primary and secondary references. In re Regel, Buchel, and Plempel, 188 U.S.P.Q. 136, 139 (CCPA 1975); Berghauser, et al. v. Dann, 204 U.S.P.Q. 393, 396 (Dist. Ct. Dist. of Columbia 1978); ACH Hospital Systems, Inc. v. Montefiore Hospital, et al., 221 U.S.P.Q. 929, 933 (CAFC 1984); and In re Imperato, 179 U.S.P.Q. 730, 732 (CCPA 1973).

In view of the Shindo, et al. reference being directed to a gas transfer process, the Applicants submit there is no incentive or motivation for combining this reference with Rasmussen and Berg. Accordingly, the Applicants submit that the combination suggested by the Examiner is improper and does not provide a prima facie case of obviousness for claims 21-58.

The Examiner has also stated that one of ordinary skill in the art would have had a reasonable expectation of success in selecting hollow fibers with pores of the required sizes such that analyte would be permeable to the desired analyte. This is tantamount to saying that it would have been obvious to try.

The standard of 35 U.S.C. 103 is not that it would have been obvious to one of ordinary skill in the art to try the invention. Disregard for unobviousness of results of "obvious to try" experiments ignores the "invention as a whole" concept of section 103. Overemphasis on routine

Docket No.: 01-11 US

nature of data gathering required to arrive at the Applicants discovery, after its existence became expected, overlooks the last sentence of section 103. In re Antonie, 195 U.S.P.Q. 6 (CCPA 1977).

"Having a reasonable expectation of success" is not the same as obviousness. The test of obviousness is whether the invention as a whole would be obvious, including the nature of the results obtained. Novo Industri A/SV Travenol Laboratories, Inc., et al., 221 U.S.P.Q. 412 (Court of Appeals 7th Circuit 1982); Ex parte Old, et al., 229 U.S.P.Q. 196 (PT and TM Office Bd. of Patent Appeals and Interferences 1985).

The Applicants submit that a prima facie case has not been made in view of the fact that with Rasmussen and Berg relate to surface phenomenon and the Shindo reference teaches gas transfer through a member separating two liquids. The Examiner has not satisfactorily explained why a person skilled in this art would have been motivated to combine the references.

In view of the amendment to specification and claims, the Applicants submit that the application is now in condition for allowance and such action is respectfully requested.

Respectfully submitted,



Walter A. Hackler, Reg. No. 27,792
Attorney of Record
2372 S.E. Bristol, Suite B
Newport Beach, California 92660
Tel: (949) 851-5010
Fax: (949) 752-1925